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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,355

05/12/2006

Frank Burkamp

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EXAMINER

BIANCHI, KRISTIN A

ART UNIT

PAPER NUMBER

4131

MAIL DATE

DELIVERY MODE

03/19/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/579,355	<b>Applicant(s)</b> BURKAMP ET AL.	
	<b>Examiner</b> KRISTIN BIANCHI	<b>Art Unit</b> 4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02/11/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 6-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5 is/are rejected.
- 7) ☒ Claim(s) 1-5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/11/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Claims 1-10 are pending in this application. Claims 6-10 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected subject matter. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference which anticipates one group would not render obvious the other.

#### **Information Disclosure Statement**

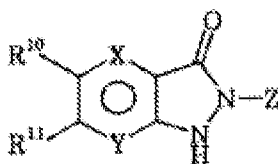
The information disclosure statement (IDS) submitted on May 11, 2006 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98 and was considered. A signed copy of form 1449 is enclosed herewith.

#### **Priority**

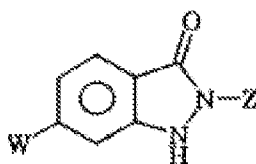
This application claims benefit of 0326633.5 (United Kingdom) filed on November 14, 2003.

#### **Response to Restriction**

Applicant's election with traverse to Group I, claims 1-5 (in part), drawn to compounds of the formulas (I) and (IA),



(I)



(IA)

and

, respectively, and the specific

compound, 1,2-Dihydro-2-(4-trifluoromethylphenyl)-6-(3-trifluoromethyl-2-

Art Unit: 1626

pyridinyl)-3H-indazol-3-one, in the response filed on February 11, 2008 is acknowledged.

The traversal is on the ground(s):

“Applicants respectfully submit that the Examiner fails to justify the restriction requirement as the present invention of Groups I-III are related. Even though only one invention may be claimed in a single application, a reasonable number of species of the invention can be claimed if there is an allowable generic claim in the application, which is the case of the present application. Accordingly, there is no additional burden on the part of the Examiner to conduct the prior art search for examination of the present application in total.”

This is not found to be persuasive. The search for the compound as claimed is not coextensive with the search for the method of using the compound or the process of making the compound. For example, in regards to the instant election (i.e. the compound and pharmaceutical composition thereof), a separate search would be required to determine the totality of the prior art that may exist that anticipates and/or makes obvious the method of using the compound and pharmaceutical composition thereof (i.e. to modulate VR1 activity).

The search was performed on the specific compound elected by the Applicant and this was then extended or broadened, however, the scope was not extended to the whole scope as presented in Claim 1. Even though an art rejection has not been made in this application, the requirement for restriction is maintained and the search has only been extended to compounds that would encompass the elected compound. It is pointed out that the restriction requirement is made under 35 U.S.C. 121 and this gives the Commissioner (Director) the authority to limit the examination of an application where two or more independent and distinct inventions are claimed to only one invention. The Examiner has indicated that more than one independent and distinct

Art Unit: 1626

invention is claimed in this application (i.e. the various compounds of Formula I) and has restricted (limited) the claimed subject matter accordingly. For example, the claims encompass heteroaryl groups which are variously classified, therefore, "heteroaryl" has been restricted out of the generic embodiment identified for examination. The following is an illustration of the varied classification of the heteroaryl groups: pyrazinyl is classified in class 544 and subclass 336+; pyrimidinyl is classified in class 544 and subclass 242+; pyridinyl is classified in class 546 and subclass 268.1+, etc. Thus, the requirement to restrict the claims in this application is predicated on the fact that the claimed subject matter involves more than one independent and distinct invention. Moreover, it would constitute a burden to extend the search because separate search consideration would be involved in both the U.S. Patents and in the literature. The examination process following the search could easily result in different and, thus, burdensome considerations.

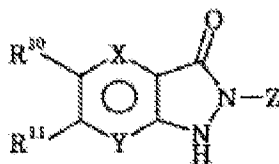
The restriction requirement here is predicated on the premise that the various compounds differ in structure and element so much so as to be patentably distinct, i.e. a reference which anticipated the elected compounds claimed would not render obvious the others. Again, 35 U.S.C. 121 gives the commissioner (Director) the authority to limit the examination of an application to a single invention. Applicant has not presented evidence that the examined subject matter is patentably indistinct from the non-examined subject matter. Moreover, the number of variables, their different possibilities, and the large number of permutations and combinations thereof result in compounds so numerous and diverse so as to be a burden to classify, search and

Art Unit: 1626

examine. Accordingly, the requirement to restrict is considered proper and is maintained. The search and examination of the application is directed to the generic embodiment identified for examination only.

The claims in the elected Group I have not been found allowable, therefore, the possibility of rejoinder of Groups II and III cannot be addressed at this time.

***The scope of the elected subject matter and the search has been extended as follows:***



Compounds of formula I,

(I)

, depicted in Claim 1, wherein:

X and Y are each CR<sup>1</sup>

R<sup>10</sup> is R<sup>1</sup>

R<sup>1</sup> is hydrogen

R<sup>11</sup> is W

W is a phenyl or pyridyl ring and is monosubstituted at the position *ortho* to the point of attachment to the rest of the molecule with trifluoromethyl, methyl or methoxy

Z is phenyl and is monosubstituted at a position *para* to the point of attachment to the rest of the molecule by trifluoromethyl

As a result of the election and the corresponding scope of the invention identified supra, the remaining subject matter of claims 1-5 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. Therefore, the subject matter which is withdrawn from consideration as being non-

elected subject matter differs materially in structure and composition and has been restricted properly. A reference which anticipates the elected subject matter would not render obvious the withdrawn subject matter and the fields of search are not coextensive.

**Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For example, it is unclear in Claim 5 what the intended use of the compound actually is. This rejection can be overcome by amending the claim to state what is to be treated in the human or animal body (i.e. which diseases or disorders) or by eliminating the word "treatment" in the claim.

**Claim Objections-Non-elected Subject Matter**

Claims 1-5 are objected to as containing non-elected subject matter. To overcome this objection, Applicant should submit an amendment deleting the non-elected subject matter.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTIN BIANCHI whose telephone number is (571)270-5232. The examiner can normally be reached on Mon-Fri 7:30-5, alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Janet Andres and Cecilia Tsang can be reached at 571-272-0867 and 571-272-0562, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kamal A Saeed, Ph.D./  
Primary Examiner, Art Unit 1626

Kristin Bianchi  
Examiner  
Art Unit 4131

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Application/Control Number: 10/579,355  
Art Unit: 1626

Page 8